IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CONFORMIS, INC., Plaintiff, v. MEDACTA USA, INC., Defendant.	Civil Action No. 19-1618-RGA **JURY TRIAL DEMANDED**

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

For its Amended Complaint against Medacta USA, Inc. ("Medacta" or "Defendant"), Plaintiff Conformis, Inc. ("Conformis" or "Plaintiff"), by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action.

2. Conformis brings this action to seek damages and other relief arising from the infringement by Medacta of (i) U.S. Patent No. 8,377,129 ("the '129 Patent," attached hereto as Exhibit A), entitled "Joint Arthroplasty Devices and Surgical Tools," (ii) U.S. Patent No. 8,460,304 ("the '304 Patent," attached hereto as Exhibit B), entitled "Joint Arthroplasty Devices and Surgical Tools," (iii) U.S. Patent No. 9,186,161 ("the '161 Patent," attached hereto as Exhibit C), entitled "Surgical Tools for Arthroplasty," and (iv) U.S. Patent No. 9,295,482 ("the '482 Patent," attached hereto as Exhibit D), entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools" (collectively, "the Patents-In-Suit").

PARTIES

3. Plaintiff Conformis, Inc. is a Delaware corporation with its worldwide headquarters at 600 Technology Park Drive, Billerica, Massachusetts 01821.

4. Conformis is the assignee and owner of the Patents-In-Suit.

5. Upon information and belief, Defendant Medacta USA, Inc. is a Delaware corporation with its principal place of business at 6640 Carothers Parkway, Franklin, Tennessee 37067.

JURISDICTION AND VENUE

6. Conformis' patent infringement claims arise under the Patent Laws of the United States, Title 35, of the United States Code and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Accordingly, this Court has subject matter jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 (federal question), 1338 (action arising under an Act of Congress relating to patents), 2201 (creation of remedy), and 2202 (further relief).

7. This Court has personal jurisdiction over Medacta, at least because Medacta is at home in the State of Delaware, where it is incorporated and has a registered agent for service of process. In addition, upon information and belief, Medacta regularly does or solicits business in the State of Delaware and has committed one or more acts of patent infringement complained of herein in the District of Delaware.

8. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400. Medacta is incorporated in Delaware and thus resides in this State.

FACTUAL BACKGROUND

A. Background

9. Conformis is the world's leading designer, developer, and manufacturer of patient-specific instrument systems required to best fit implants into a specific patient's body. Conformis also designs and manufactures patient-specific knee and hip replacement implant systems. Founded by doctors affiliated with Stanford and Harvard Medical Schools, Conformis

began with a revolutionary idea: make the implant and tools fit the patient rather than forcing the patient to fit the implant and tools.

10. For decades before Conformis' innovation, surgeons have been implanting medical devices using (and many are still using) standard instrument systems that have not been designed with reference to the anatomy of individual patients. As a result of this imprecise approach, after surgery, patients commonly suffer loss of movement and function, instability, and lingering pain.

11. Conformis recognized that the conventional process of joint repair was backwards: rather than fitting the patient to the tools, the tools should be designed and developed specifically for the patient, as this produces a better-seated implant.

12. Conformis therefore set out to develop patient-specific instrument systems, which precisely place an implant, reduce surgical time and trauma, and create a reproducible surgical technique. Conformis' patient-specific instrument systems eliminate many of the traditional instruments associated with conventional surgery while concurrently simplifying and improving surgical technique.

B. Conformis' Patents

13. Conformis has made significant investments in the research, development, and testing of patient-specific instrument systems for knee and hip replacement surgery.

14. To protect those investments, Conformis applied for and obtained a number of patents, including the Patents-In-Suit.

15. Patent authorities worldwide have recognized that Conformis' patient-specific instrument systems are worthy of patent protection, and have granted Conformis over 200 patents on its technologies. These patents, and Conformis' many additional pending patent

applications, span a range of related technologies including imaging software, image processing, patient-specific orthopedic implants, patient-specific orthopedic instrumentation, methods of design and manufacture of patient-specific systems, and related surgical techniques. The technology and patent portfolio are applicable to all major joint systems, including knee, hip, shoulder, and ankle joints.

16. The ’129 Patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on February 19, 2013, to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis and Rene Vargas-Voracek, after fair and full examination, for “Joint Arthroplasty Devices and Surgical Tools.” The ’129 Patent is assigned to Conformis.

17. The ’304 Patent was duly and legally issued by the USPTO on June 11, 2013, to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis and Rene Vargas-Voracek, after full and fair examination, for “Joint Arthroplasty Devices and Surgical Tools.” The ’304 Patent is assigned to Conformis.

18. The ’161 Patent was duly and legally issued by the USPTO on November 17, 2015, to Philipp Lang, Wolfgang Fitz, Ray Bojarski, Daniel Steines, Albert G. Burdulis, Jr., and Rene Vargas-Voracek, after fair and full examination, for “Surgical Tools for Arthroplasty.” The ’161 Patent is assigned to Conformis.

19. The ’482 Patent was duly and legally issued by the USPTO on March 29, 2016, to Wolfgang Fitz, Philipp Lang, Raymond A. Bojarski and Daniel Steines, after fair and full examination, for “Patient Selectable Joint Arthroplasty Devices and Surgical Tools.” The ’482 Patent is assigned to Conformis.

20. Conformis is the owner of all rights, title, and interest in and to the Patents-In-Suit. Conformis possesses all rights to sue and recover for past and future infringement of the Patents-In-Suit.

C. Medacta's Infringing Activities[1]

21. Medacta offers the MyKnee® "patient-specific" instruments that are "based on CT or MRI images of the patient's knee" for knee replacement surgery, including at least MyKnee® Ligament Balancing System ("MyKnee® LBS") (*see* Ex. E at 4), MyKnee® Minimally Invasive Cutting Blocks ("MyKnee® MIS"), MyKnee® Pin Positioning System ("MyKnee® PPS") and MyKnee® Uni Cutting Block ("MyKnee® Uni") (collectively, "MyKnee®").

22. MyKnee® is used with different Medacta implants, including Global Medacta Knee ("GMK") Primary, GMK Sphere and GMK Uni (collectively, "My Knee® Implants").

23. Medacta also offers other products that are used with MyKnee®, including at least the following product lines: GMK Efficiency, Efficiency KneePack, and MyKnee MIKA instruments.

24. Medacta also offers patient matched technology in the form of patient-specific instruments for shoulder surgery, including at least MyShoulder products.

25. On information and belief, MyShoulder can be used with the Medacta Shoulder System. The Medacta Shoulder System is comprised of various implant components of varying sizes.

26. Medacta's instruments and products compete with Conformis' innovative patient-specific surgical products.

[1] Based on Medacta's representations, Conformis has removed allegations against Medacta's MyHip without prejudice.

27. On information and belief, Medacta is, or soon will be, infringing the Patents-In-Suit by making, using, providing, offering to sell, importing, and selling (directly or through intermediaries) at least MyKnee® and MyShoulder patient-specific instruments and implants, including the MyKnee® Implants and the Medacta Shoulder System, in this District and elsewhere in the United States.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,377,129

28. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

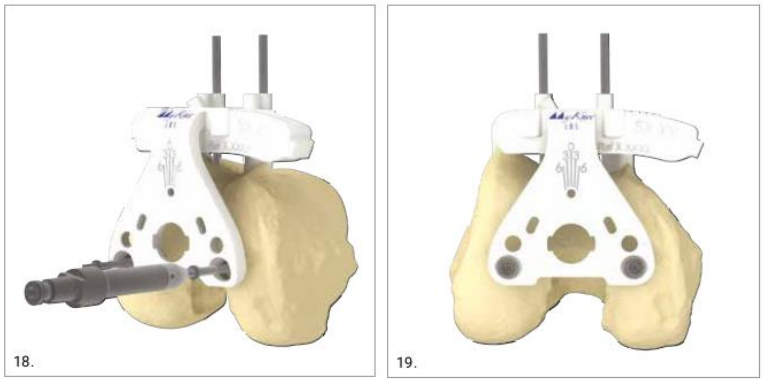
29. On information and belief, Medacta is presently making, using, offering for sale, and/or selling a patient-specific system for knee surgery, including MyKnee® and MyKnee® Implants (together, the "MyKnee® System"), that directly infringes one or more claims of the '129 Patent, literally or under the doctrine of equivalents.

30. Medacta's system practices at least one claim of the '129 Patent. For example, claim 1 recites:

> A patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient, the instrument system comprising:
>
> > a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient,
> >
> > > the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient; and
> > >
> > > a guide for directing a surgical instrument,
> > >
> > > > wherein the guide has a predetermined position relative to the patient-specific surface and a predetermined orientation relative to at least one of an anatomical axis and a biomechanical axis associated with said knee joint;
> > > >
> > > > wherein the guide defines a drilling path through at least a portion of the knee joint,

> the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.

31. Claim 1 of the ’129 Patent recites “[a] patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient,” comprising “a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the” knee joint, which includes “cartilage information derived from image data” of the knee joint and also includes “a guide for directing a surgical instrument.” Ex. A at Claim 1. Medacta’s MyKnee® is a “patient-specific” instrument that is “based on . . . MRI images of the patient’s knee” (Ex. E at 4) and is “designed for a single patient to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.” *Id.* Additionally, the MyKnee® is “fixed . . . using . . . cortical pins.” *Id.* at 14. The images below are illustrative:

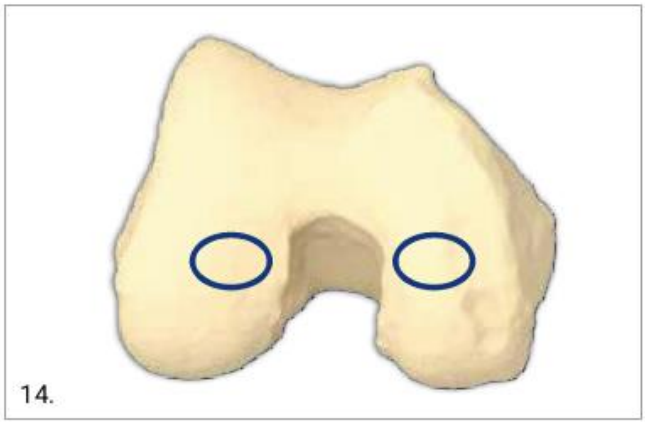


Id.

32. Claim 1 of the ’129 Patent also recites that “the guide has a predetermined position relative to the patient-specific surface and a predetermined orientation relative to . . . an anatomical axis [or] a biomechanical axis associated” with the knee joint and “defines a drilling path through at least a portion of the knee joint . . . based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.” Ex. A at Claim 1. The MyKnee® technique guide instructs the operator to verify that the points of contact between the cutting

block and the bone are "respected." Ex. E at 12. The image below is illustrative and the brochure states that the cutting block contact area is based on the CT and MRI imaging. *Id.*

To ensure the maximum stability, verify that the points of contact between the MyKnee distal cutting block and the femur are respected. If bone models are available ensure that the contact points between MyKnee block and bone are in the position of the areas marked on the bone model. CT based and MRI based cutting blocks use different contact areas.



○ MyKnee LBS distal cutting block contact area on the distal condyles

Id.. The MyKnee® technique guide instructs that the particular "parameters regarding femoral and tibial implantation" are planned by the surgeon before the surgical procedure, some of which include "femoral rotation" and "angles." *Id.* at 4. During surgery, which includes MyKnee® Implants, "[t]he surgeon can decide to fix the external rotation selected in the pre-operative planning . . . by inserting a pin in the central hole." *Id.* at 17.

33. Medacta's infringing activities violate one or more subsections of 35 U.S.C. § 271.

34. Medacta has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '129 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the

’129 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing MyKnee® System, as detailed above. Medacta’s active inducement has included, for example and without limitation, marketing, selling, and offering to sell the MyKnee® System, providing instructions on how to use the MyKnee® System, selling instrumentation or devices for use with the MyKnee® System, and promoting the use of the MyKnee® System. For example, Medacta has encouraged customers including scientists, researchers, and health care professionals to use the MyKnee® System by means of marketing materials and videos. Medacta also has instructed customers on how to use the MyKnee® System by means of product manuals.

35. Medacta has also contributed, and continues to contribute, to its customers’ direct infringement of the ’129 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.

36. Upon information and belief, at least as early as the filing of the original Complaint, Medacta knows and/or is willfully blind to the fact that Medacta’s actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the ’129 Patent with the knowledge and intent that one or more claims of the ’129 Patent be infringed.

37. Medacta has had notice of the ’129 Patent at least as early as the filing of the original Complaint. On information and belief, Medacta’s direct and indirect infringement of the ’129 Patent has been willful.

38. Conformis has suffered economic harm as a result of Medacta’s infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,460,304

39. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

40. On information and belief, Medacta is presently making, using, offering for sale, and/or selling patient-specific systems for knee surgery, including MyKnee® System, and shoulder surgery, including MyShoulder products, that directly infringe one or more claims of the ’304 Patent, literally or under the doctrine of equivalents.

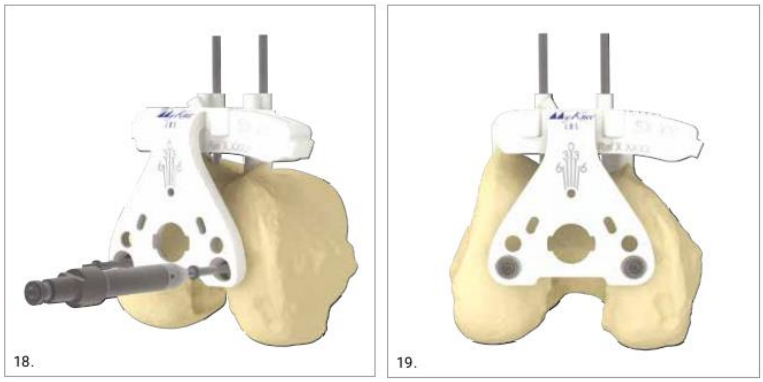
41. Medacta’s systems practice at least one claim of the ’304 Patent. For example, claim 1 recites:

> A surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:
>
> > a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and
> >
> > two or more guide holes, each configured to guide a surgical pin,
> >
> > > wherein at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient,
> > >
> > > > wherein the articular repair system has a predetermined rotation angle and
> > > >
> > > > wherein the position is based on the predetermined rotation angle.

42. Claim 1 of the ’304 Patent requires that the “surgical instrument for use in surgically repairing a joint of a patient . . . ha[s] an internal surface that includes joint information derived from image data of the joint of the patient.” Ex. B at Claim 1. Medacta’s MyKnee® is a “patient-specific” instrument that is “based on CT or MRI images of the patient’s knee” (Ex. E at 4) and is “designed for a single patient to assist in the positioning of total knee

replacement components intraoperatively and in guiding the marking of bone before cutting." *Id.*

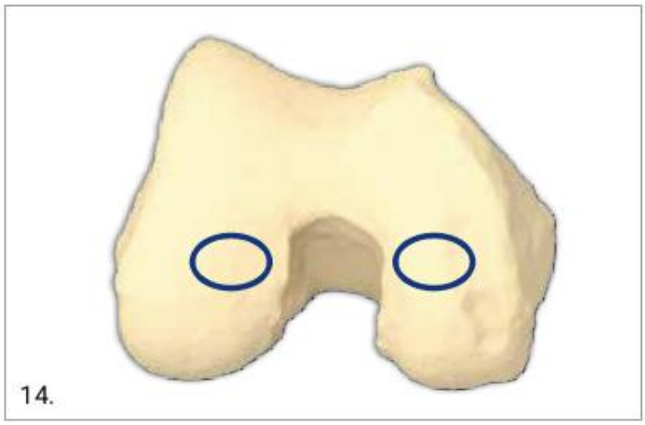
43. Claim 1 of the '304 Patent also recites that the claimed instrument has "two or more guide holes, each configured to guide a surgical pin." Ex. B at Claim 1. Similarly, the MyKnee® is "fixed . . . using . . . cortical pins." Ex. E at 14. The images below are illustrative:



Id.

44. In addition, claim 1 of the '304 Patent requires that "at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient." Ex. B at Claim 1. The MyKnee® technique guide instructs the operator to verify that the points of contact between the cutting block and the bone are "respected." Ex. E at 12. The image below is illustrative and the brochure states that the cutting block contact area is based on the CT and MRI imaging. *Id.*

To ensure the maximum stability, verify that the points of contact between the MyKnee distal cutting block and the femur are respected. If bone models are available ensure that the contact points between MyKnee block and bone are in the position of the areas marked on the bone model. CT based and MRI based cutting blocks use different contact areas.



○ MyKnee LBS distal cutting block contact area on the distal condyles

Id.

45. Lastly, claim 1 of the '304 Patent recites that the "articular repair system has a predetermined rotation angle and . . . the position is based on the predetermined rotation angle." Ex. B at Claim 1. The MyKnee® technique guide instructs that the particular "parameters regarding femoral and tibial implantation" are planned by the surgeon before the surgical procedure, some of which include "femoral rotation" and "angles." Ex. E at 4. During surgery including MyKnee® Implants, "[t]he surgeon can decide to fix the external rotation selected in the pre-operative planning . . . by inserting a pin in the central hole." *Id.* at 17.

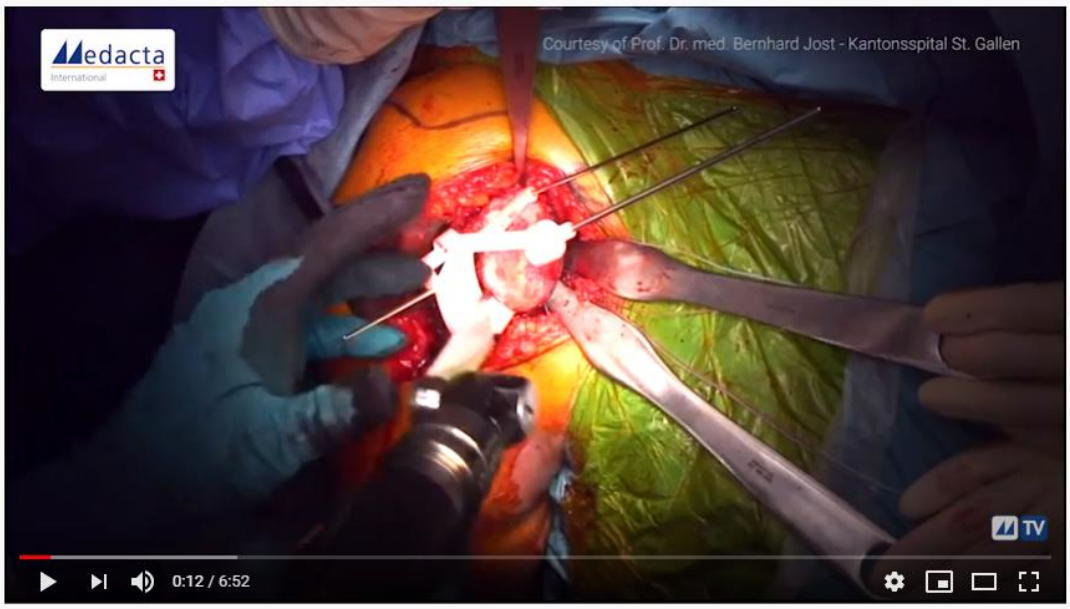
46. The MyShoulder instrument system as used with the Medacta Shoulder System infringes the '304 Patent in a similar manner.

47. As stated above, claim 1 of the '304 patent recites "[a] surgical instrument for use in surgically repairing a joint of a patient." Ex. B at Claim 1. Medacta's MyShoulder instrument

system is a surgical instrument for use in surgically repairing a joint of a patient. MyShoulder allows "a surgeon to realize the pre-operative 3D planning and deliver accurate implant placement using CT based 3D printed cutting and pin guides" (Ex. F at 1) and is used with the Medacta Shoulder System components. Ex. G at 1-2.

48. Claim 1 of the '304 patent requires the surgical instrument to have "a mold having an internal surface that includes joint information derived from image data of the joint of the patient." Ex. B at Claim 1. MyShoulder relies on CT images of the patient's shoulder to prepare patient-specific guides and virtually position the implant before surgery. Ex. F at 1-2.

49. Claim 1 of the '304 patent additionally requires that the surgical instrument have "two or more guides holes, each configured to guide a surgical pin." Ex. B at Claim 1. MyShoulder has two or more guide holes, each of which is configured to guide a surgical pin:



Medacta Shoulder System Reverse Live Surgery with Bio-RSA using MyShoulder - Prof. Dr. Med. B. Jost

See https://www.youtube.com/watch?v=qvT0Ml-KiNk. Claim 1 of the '304 patent further requires that "at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system

when the internal surface of the mold is aligned with the joint of the patient" and that the articular repair system has a predetermined rotation angle, on which the position is based. Ex. B at Claim 1. MyShoulder is used with the Medacta Shoulder System components. Ex. G at 1-2. Using the MyShoulder workflow, CT images of the patient's shoulder are taken to prepare a patient-specific guide, engage in preoperative planning and virtually position the implant. Ex. F at 1-2. Therefore, at least one of the two or more MyShoulder guide holes has a position based on anatomical information of the patient to facilitate the placement of the articular repair system when the mold is aligned with the patient's joint.

50. Medacta's infringing activities violate one or more subsections of 35 U.S.C. § 271.

51. Medacta has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '304 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '304 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing MyKnee® System and MyShoulder products, as detailed above. Medacta's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the MyKnee® System and MyShoulder; providing instructions on how to use the MyKnee® System and MyShoulder; selling instrumentation or devices for use with the MyKnee® System and MyShoulder; and promoting the use of the MyKnee® System and MyShoulder. For example, Medacta has encouraged and/or will encourage customers including scientists, researchers, and health care professionals to use the MyKnee® System and MyShoulder by means of marketing materials and videos. Medacta also

has instructed and/or will instruct customers on how to use the MyKnee® System and MyShoulder by means of product manuals.

52. Medacta has also contributed, and continues to contribute, to its customers' direct infringement of the '304 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.

53. Upon information and belief, at least as early as the filing of the original Complaint, Medacta knows and/or is willfully blind to the fact that Medacta's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '304 Patent with the knowledge and intent that one or more claims of the '304 Patent be infringed.

54. Medacta has had notice of the '304 Patent at least as early as the filing of the original Complaint. On information and belief, Medacta's direct and indirect infringement of the '304 Patent has been willful.

55. Conformis has suffered economic harm as a result of Medacta's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,186,161

56. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

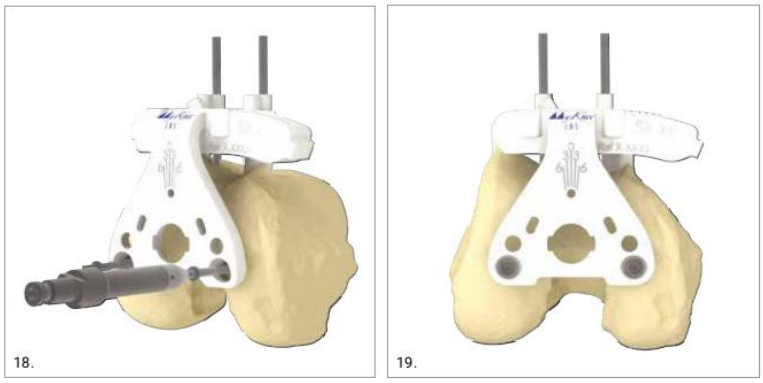
57. On information and belief, Medacta is presently making, using, offering for sale, and/or selling patient-specific systems for knee surgery, including MyKnee® System, and shoulder surgery, including MyShoulder products, that directly infringe one or more claims of the '161 Patent, literally or under the doctrine of equivalents.

58. Medacta's system practices at least one claim of the '161 Patent. For example, claim 1 recites:

> A surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:
>
> > a mold having an internal surface that includes joint information derived from image data of the joint of the patient;
> >
> > and two or more guide holes, each configured to guide a surgical pin,
> >
> > > wherein at least one of the two or more guide holes has a position and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the joint of the patient,
> > >
> > > > wherein the articular repair system has a predetermined rotation angle and wherein the position and/or orientation is based on the predetermined rotation angle.

59. Claim 1 of the ’161 Patent recites a “surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient” that comprises “a mold having an internal surface that includes joint information derived from image data of the joint of the patient.” Ex. C at Claim 1. Medacta’s MyKnee® is “designed for a single patient to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.” Ex. E at 4. Prior to the surgical procedure, “CT or MRI imaging is used to create a tri-dimensional bone model of the patient’s knee anatomy. This bone replica is the model used to create the anatomical cutting blocks that can fit a patient’s knee morphology . . . .” *Id.*

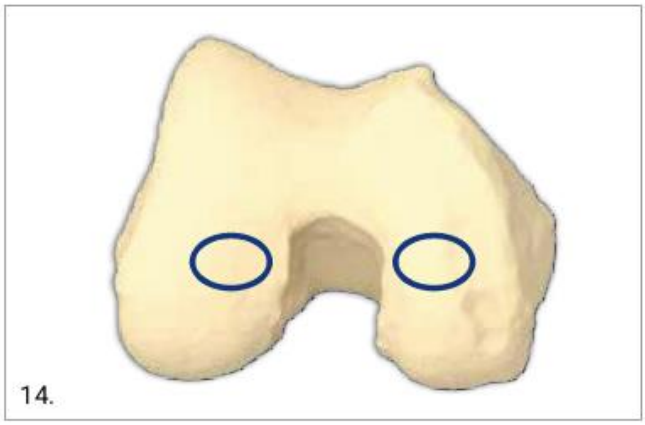
60. Claim 1 of the ’161 Patent also requires the claimed invention to have “two or more guide holes, each configured to guide a surgical pin.” Ex. C at Claim 1. The MyKnee® technique guide instructs that in order to fix the MyKnee® on the femur and to “avoid [anterior/posterior] movement,” it “must . . . be fixed on the femoral distal condyles using . . . cortical pins.” Ex. E at 14. The images below are illustrative:



Id.

61. Claim 1 of the ’161 Patent further recites that the “guide holes ha[ve] a position and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the joint of the patient.” Ex. C at Claim 1. The MyKnee® technique guide instructs the operator to verify that the points of contact between the instrument and the bone are “respected.” Ex. E at 12. The image below is illustrative and the MyKnee® brochure states that the cutting block contact area is based on the CT and MRI imaging data. *Id.*

To ensure the maximum stability, verify that the points of contact between the MyKnee distal cutting block and the femur are respected. If bone models are available ensure that the contact points between MyKnee block and bone are in the position of the areas marked on the bone model. CT based and MRI based cutting blocks use different contact areas.



○ MyKnee LBS distal cutting block contact area on the distal condyles

Id. The MyKnee® technique guide instructs that the particular "parameters regarding femoral and tibial implantation" are planned by the surgeon before the surgical procedure, some of which include "femoral rotation" and "angles." *Id.* at 4.

62. Lastly, claim 1 of the '161 Patent requires that the "articular repair system" have "a predetermined rotation angle . . . wherein the position and/or orientation is based on the predetermined rotation angle." Ex. C at Claim 1. Moreover, for the MyKnee® including MyKnee® Implants, the particular "parameters regarding femoral and tibial implantation" are planned by the surgeon prior to the surgical procedure, and include "femoral rotation" and "angles." Ex. E at 4. During surgery, "[t]he surgeon can decide to fix the external rotation selected in the pre-operative planning . . . by inserting a pin in the central hole." *Id.* at 17.

63. MyShoulder as used with the Medacta Shoulder System infringes the '161 Patent in a similar manner.

64. As stated above, claim 1 of the ’161 patent recites “[a] surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient.” Ex. C at Claim 1. Medacta’s MyShoulder as used with Medacta Shoulder System is a surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient. MyShoulder allows “a surgeon to realize the pre-operative 3D planning and deliver accurate implant placement using CT based 3D printed cutting and pin guides” (Ex. F at 1) and is used with the Medacta Shoulder System components. Ex. G at 1-2.

65. Claim 1 of the ’161 patent requires the surgical instrument to have “a mold having an internal surface that includes joint information derived from image data of the joint of the patient.” Ex. C at Claim 1. MyShoulder relies on CT images of the patient’s shoulder to prepare patient-specific guides and virtually position the implant before surgery. Ex. F at 1-2.

66. Claim 1 of the ’161 patent additionally requires that the surgical instrument have “two or more guides holes, each configured to guide a surgical pin.” Ex. C at Claim 1. MyShoulder has two or more guide holes, and on information and belief, each guide hole is configured to guide a surgical pin:

Medacta Shoulder System Reverse Live Surgery with Bio-RSA using MyShoulder - Prof. Dr. Med. B. Jost

See https://www.youtube.com/watch?v=qvT0Ml-KiNk. Claim 1 of the '161 patent further requires that "at least one of the two or more guide holes has a position and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the joint of the patient" and that the articular repair system has a predetermined rotation angle, on which the position is based. Ex. C at Claim 1. MyShoulder is used with the Medacta Shoulder System components. Ex. G at 1-2. Using the MyShoulder workflow, CT images of the patient's shoulder are taken to prepare a patient-specific guide, engage in preoperative planning and virtually position the implant. Ex. F at 1-2. Therefore, at least one of the two or more MyShoulder guide holes has a position based on anatomical information of the patient to facilitate the placement of the articular repair system when the mold is aligned with the patient's joint.

67. Medacta's infringing activities violate one or more subsections of 35 U.S.C. § 271.

68. Medacta has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '161 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '161 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing MyKnee® System and MyShoulder, as detailed above. Medacta's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the MyKnee® System and MyShoulder; providing instructions on how to use the MyKnee® System and MyShoulder; selling instrumentation or devices for use with the MyKnee® System and MyShoulder; and promoting the use of the MyKnee® System and MyShoulder. For example, Medacta has encouraged and/or will encourage, and continues to encourage, customers including scientists, researchers, and health care professionals to use the MyKnee® System and MyShoulder by means of marketing materials and videos. Medacta also has instructed and/or will instruct customers on how to use the MyKnee® System and MyShoulder by means of product manuals.

69. Medacta has also contributed, and continues to contribute, to its customers' direct infringement of the '161 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.

70. Upon information and belief, at least as early as the filing of the original Complaint, Medacta knows and/or is willfully blind to the fact that Medacta's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '161 Patent with the knowledge and intent that one or more claims of the '161 Patent be infringed.

71. Medacta has had notice of the ’161 Patent at least as early as the filing of the original Complaint. On information and belief, Medacta’s direct and indirect infringement of the ’161 Patent has been willful.

72. Conformis has suffered economic harm as a result of Medacta’s infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 9,295,482

73. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

74. On information and belief, Medacta is presently making, using, offering for sale, and/or selling a patient-specific system for knee surgery, including MyKnee® System, that directly infringes one or more claims of the ’482 Patent, literally or under the doctrine of equivalents.

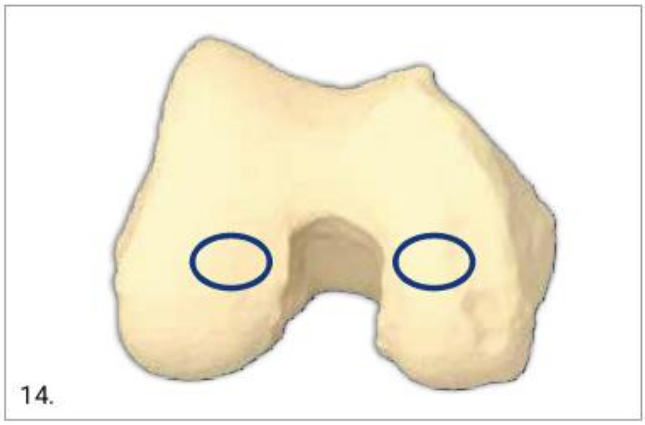
75. Medacta’s system practices at least one claim of the ’482 Patent. For example, claim 13 recites:

> A joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, comprising:
>
> an implant; and
>
> a block having a patient-specific surface and a guide:
>
> the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,
>
> wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint; and
>
> the guide being sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path

> for the surgical tool that is aligned through a portion of the diseased or damaged joint.

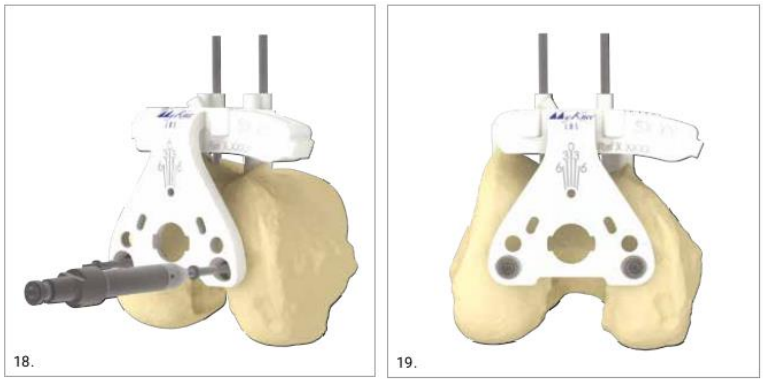
76. Claim 13 of the ’482 Patent recites a “joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient,” which comprises an “implant,” a “patient-specific . . . block” and “a guide.” Ex. D at Claim 13. Medacta’s MyKnee® is a “patient-specific cutting block which allows the surgeon to realise his pre-operative 3D planning, based on CT or MRI images of the patient’s knee.” Ex. E at 4. The system is “designed for a single patient to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.” *Id.* Prior to the surgical procedure, “CT or MRI imaging is used to create a tri-dimensional bone model of the patient’s knee anatomy. This bone replica is the model used to create the anatomical cutting blocks that can fit a patient’s knee morphology . . . .” *Id.* Prior to the surgical procedure, the surgeon is involved in “preoperative planning . . . to assess the surgical parameters regarding femoral and tibial implantation. . . . [These] [p]arameters . . . include: [f]emoral implant size [and] [t]ibial implant size.” *Id.* The technique guide instructs the operator to verify that the points of contact between the instrument and the bone are “respected.” *Id.* at 12. The image below is illustrative and the brochure states that the cutting block contact area is based on the CT and MRI imaging. *Id.*

To ensure the maximum stability, verify that the points of contact between the MyKnee distal cutting block and the femur are respected. If bone models are available ensure that the contact points between MyKnee block and bone are in the position of the areas marked on the bone model. CT based and MRI based cutting blocks use different contact areas.



○ MyKnee LBS distal cutting block contact area on the distal condyles

Id. In order to fix the MyKnee® on the femur and to "avoid [anterior/posterior] movement," it "must also be fixed on the femoral distal condyles using . . . cortical pins." *Id.* at 14. The images below are illustrative:



Id.

77. Additionally, claim 13 of the '482 Patent requires the "patient-specific surface . . . to reference an osteophyte of the diseased or damaged joint." Ex. D at Claim 13. MyKnee®

warns the surgeon not to "remove any osteophytes from the tibia or from the femur, in order not to alter the bony references of the MyKnee anatomical cutting blocks." *Id.* at 8, 11.

78. Claim 13 of the '482 Patent additionally recites that the claimed instrument contacts "subchondral bone surface of the diseased or damaged joint" and "cortical bone surface of the diseased or damaged joint." Ex. D at Claim 13. On information and belief, the MyKnee® contacts both cortical bone and subchondral bone because the surgeon is instructed to "remove . . . cartilage . . . covering the cutting block contact areas." Ex. E at 12. On information and belief, the following image is illustrative of the contact MyKnee® makes with subchondral and cortical bone:

Id. at 18.

79. Additionally, claim 13 of the '482 Patent requires the "guide" to be "sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint." Ex. D at Claim 13. The MyKnee® guide instructs that "[o]nce the cutting guide has been properly arranged . . ., cut parameters are automatically set for the knee undergoing surgery according to the pre-operative planning. . . ." Ex. E at 13.

80. Medacta's infringing activities violate one or more subsections of 35 U.S.C. § 271.

81. Medacta has also actively induced, and continues to actively induce, others to infringe at least claim 13 of the '482 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 13 of the '482 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing MyKnee® System, as detailed above. Medacta's active inducement has included, for example and without limitation, marketing, selling, and offering to sell the MyKnee® System, providing instructions on how to use the MyKnee® System, selling instrumentation or devices for use with the MyKnee® System, and promoting the use of the MyKnee® System. For example, Medacta has encouraged customers including scientists, researchers, and health care professionals to use the MyKnee® System by means of marketing materials and videos. Medacta also has instructed customers on how to use the MyKnee® System by means of product manuals.

82. Medacta has also contributed, and continues to contribute, to its customers' direct infringement of the '482 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.

83. Upon information and belief, at least as early as the filing of the original Complaint, Medacta knows and/or is willfully blind to the fact that Medacta's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '482 Patent with the knowledge and intent that one or more claims of the '482 Patent be infringed.

84. Medacta has had notice of the ’482 Patent at least as early as the filing of the original Complaint. On information and belief, Medacta’s direct and indirect infringement of the ’482 Patent has been willful.

85. Conformis has suffered economic harm as a result of Medacta’s infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

COUNT V: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT 8,460,304

86. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

87. On information and belief, to the extent it does not already do so, Medacta will soon be making, using, selling, importing, or offering for sale the MyShoulder instrument system in the United States, which will directly or indirectly infringe valid and enforceable claims of the ’304 patent, as detailed above. For example, Medacta’s United States webpage advertises the availability of MyShoulder, noting that “[t]he Medacta Shoulder System is a modular solution that features a broad range of options, including . . . the *CT-based MyShoulder 3D* preoperative planning solution.” *See* http://www.medacta.us.com/US/shoulder-anatomic-q3-2017 (emphasis added). Additionally, on December 17, 2019, Medacta announced that it received FDA Clearance for MyShoulder. *See* https://www.medacta.com/EN/press?newsID=1874971. On information and belief, Medacta sought and received FDA Clearance to imminently begin selling MyShoulder in the United States. This situation presents an actual and immediate controversy under the Declaratory Judgment Act.

88. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,186,161

89. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

90. On information and belief, to the extent it does not already do so, Medacta will soon be making, using, selling, importing, or offering for sale the MyShoulder instrument system in the United States, which will directly or indirectly infringe valid and enforceable claims of the '161 patent, as detailed above. For example, Medacta's United States webpage advertises the availability of MyShoulder, noting that "[t]he Medacta Shoulder System is a modular solution that features a broad range of options, including . . . the *CT-based MyShoulder 3D* preoperative planning solution." *See* http://www.medacta.us.com/US/shoulder-anatomic-q3-2017 (emphasis added). Additionally, on December 17, 2019, Medacta announced that it received FDA Clearance for MyShoulder. *See* https://www.medacta.com/EN/press?newsID=1874971. On information and belief, Medacta sought and received FDA Clearance to imminently begin selling MyShoulder in the United States. This situation presents an actual and immediate controversy under the Declaratory Judgment Act.

91. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

PRAYER FOR RELIEF

WHEREFORE, Conformis respectfully requests the following relief:

A. The entry of a judgment in favor of Conformis, and against Medacta, that Medacta has infringed and is continuing to infringe one or more claims of the '129 Patent, the '304 Patent, the '161 Patent and/or the '482 Patent and declaring that Medacta's importing, making, using, offering to sell, and/or selling at least MyShoulder products in the United States

are and would be acts of infringement of one or more claims of the'304 Patent and/or the '161 Patent.

B. The entry of a judgment in favor of Conformis, and against Medacta, that Medacta has willfully infringed one or more claims of the '129 Patent, the'304 Patent, the '161 Patent and/or the '482 Patent;

C. The entry of a judgment awarding Conformis all damages resulting from Medacta's infringement, including Conformis' lost profits and no less than a reasonable royalty, and that such amount be trebled based on Medacta's willful infringement;

D. The entry of a judgment declaring that this is an exceptional case and awarding Conformis its attorneys' fees in this matter pursuant to 35 U.S.C. § 285;

E. The entry of a judgment in favor of Conformis, and against Medacta, that interest, costs, and expenses be awarded in favor of Conformis; and

F. That this Court order such other relief as the Court may deem just and proper, including injunctive relief.

JURY DEMAND

Conformis hereby demands trial by jury in this action on all issues so triable.

Dated: December 23, 2019

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

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* Admitted only in New York; practicing law in the District of Columbia during the pendency of her application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar.

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